Christina L. Saveriano
Eric I. Abraham
HILL WALLACK, LLP
21 Rozel Road
Princeton, NJ 08543
Telephone: (609) 924-0808
Facsimile: (609) 452-1888

Of Counsel:
Bryan S. Hales
Alyse Wu
Kyle M. Kantarek
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200

Stefan M. Miller
KIRKLAND & ELLIS LLP
601 Lexington Ave.
New York, NY 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900

Sean M. McEldowney
KIRKLAND & ELLIS LLP
655 15th St., N.W.
Washington, DC 20005
Telephone: (202) 879-5000
Facsimile: (202) 879-5200

Attorneys for Defendants-Counter Claimants Sandoz Inc. and Alcon Laboratories, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Allergan Sales, LLC Allergan, Inc., Plaintiffs-Counter Defendants, *v.* Sandoz Inc. Alcon Laboratories, Inc., Defendants-Counter Claimants.	Civil Action No.: 2:17-cv-10129 (WHW-CLW) *Filed Electronically*

SANDOZ INC.'S AND ALCON LABORATORIES, INC.'S BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS DEFENDANTS' INEQUITABLE CONDUCT AND ANTITRUST COUNTERCLAIMS AND TO STRIKE DEFENDANTS' TENTH AFFIRMATIVE DEFENSE, OR ALTERNATIVELY TO BIFURCATE AND STAY DEFENDANTS' ANTITRUST COUNTERCLAIMS

TABLE OF CONTENTS

INTRODUCTION **1**

BACKGROUND **4**

A. Allergan's Clinical Studies 6

B. Allergan's Prosecution of the Combigan-Family Patents 9

ARGUMENT **13**

I. SANDOZ'S INEQUITABLE CONDUCT AND ANTITRUST COUNTERCLAIMS ARE NOT COMPULSORY COUNTERCLAIMS THAT COULD HAVE BEEN RAISED IN PRIOR LITIGATIONS **14**

II. SANDOZ'S INEQUITABLE CONDUCT CLAIMS ARE PLAUSIBLE **17**

A. Sandoz Has Plausibly Pled that Allergan Intentionally Submitted a False Affidavit to and Withheld Material Information from the Patent Office 19

B. Each Basis of Inequitable Conduct Alleged by Sandoz is Plausible 23

1. Allergan Submitted the Material and False Schiffman Declaration with a Specific Intent to Deceive the PTO (Basis 2) (¶¶ 211–249) 23

2. Allergan Failed to Disclose the Material Duh Report with the Specific Intent to Deceive the PTO (Basis 3) (¶¶ 250–265) 27

3. Allergan Misrepresented to the PTO Combigan's Performance Compared to the "Closest Prior Art" (Basis 1) (¶¶ 185–210) 29

4. Allergan Failed to Disclose Material Clinical Data and FDA Criticisms with Specific Intent to Deceive the PTO (Bases 1, 2, 4, 5, 7, 8) (¶¶ 185–210, 211–249, 266–291, 292–306, 331–351, 352–369) 31

5. Allergan Failed to Disclose the Material David Reference with the Specific Intent to Deceive the PTO (Basis 6) (¶¶ 307–330) 32

6. Allergan Buried Material Information with the Specific Intent to Deceive the PTO (Basis 8) (¶¶ 352-369) 33

III. SANDOZ'S ANTITRUST CLAIMS ARE PLAUSIBLE **35**

CONCLUSION **39**

TABLE OF AUTHORITIES

Page(s)

Cases

Abbott Labs. v. Teva Pharm. USA, Inc.,
432 F. Supp. 2d 408 (D. Del. 2006) 35

Allergan, Inc. v. Sandoz Inc.,
726 F.3d 1286 (Fed. Cir. 2013) 5

Am. Packaging Corp. v. Golden Valley Microwave Foods, Inc.,
No. 94-cv-1839, 1995 WL 262522 (E.D. Pa. 1995) 16

Auxilium Pharms., Inc. v. Watson Labs., Inc.,
No. 12-cv-3084, 2013 WL 5503209 (D.N.J. 2013) 18, 21

B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.,
72 F.3d 1577 (Fed. Cir. 1996) 29

Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.,
267 F.3d 1370 (Fed. Cir. 2001) 28

Brenner v. Local 514 United Bros. of Carpenters of Am.,
927 F.3d 1283 (3d Cir. 1991) 35

Bristol-Myers Squibb Co. v. Ben Venue Labs.,
90 F. Supp. 2d 522 (D.N.J. 2000) 30

Bruni v. City of Pittsburgh,
824 F.3d 353 (3d Cir. 2016) 13

Cal. Motor Transp. v. Trucking Unlimited,
404 U.S. 508 (1972) 36, 37

CIVIX-DDI, LLC v. Hotels.com, L.P.,
711 F. Supp. 2d 839 (N.D. Ill. 2010) 33

Consol. Aluminum Corp. v. Fonseco Int'l Ltd.,
910 F.2d 804 (Fed. Cir. 1990) 30

Coolsystems, Inc. v. Nice Recovery Sys. LLC,
No. 16-cv-02958, 2016 WL 6091577 (N.D. Cal. 2016) 33

Cuozzo Speed Techs., LLC v. Lee,
136 S. Ct. 2131 (2016) 28

Delano Farms Co. v. Cal. Table Grape Comm'n,
655 F.3d 1337 (Fed. Cir. 2011).....18, 21

Depomed, Inc. v. Purdue Pharma L.P.,
No. 13-cv-571, 2017 WL 2804953 (D.N.J. 2017).....17, 18, 21, 29

Dow Chem. Co. v. Melton Corp.,
281 F.2d 292 (4th Cir. 1960).....1, 14

eSpeed, Inc. v. Brokertec USA, L.L.C.,
417 F. Supp. 2d 580 (D. Del. 2006).....30

Exergen Corp. v. Wal-Mart Stores, Inc.,
575 F.3d 1312 (Fed. Cir. 2009).....18, 21

Fowler v. UPMC Shadyside,
578 F.3d 203 (3d Cir. 2009).....13

Goodman Mfg. Co. v. Carrier Corp.,
No. 13-cv-2014, 2014 WL 4954281 (D. Del. 2014).....16

Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.,
806 F.3d 162 (3d Cir. 2015).....36

Hedges v. United States,
404 F.3d 744 (3d Cir. 2005).....13

Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.,
No. 00-cv-1167, 2010 WL 1372176 (D.N.J. 2010).....18

Indus. Tech. Research Inst. v. LG Corp.,
No. 12-cv-929, 2012 WL 4469383 (D.N.J. 2012).....13, 18, 21, 26, 27

Intellect Wireless, Inc. v. HTC Corp.,
732 F.3d 1339 (Fed. Cir. 2013).....23

Iovate Health Sci., Inc. v. Allmax Nutrition, Inc.,
639 F. Supp. 2d 115 (D. Mass. 2009).....27

Kearns v. Gen. Motors Corp.,
94 F.3d 1553 (Fed. Cir. 1996).....14

Keystone Driller Co. v. General Excavator Co.,
290 U.S. 240 (1933).....30

LePage's, Inc. v. 3M,
324 F.3d 141 (3d Cir. 2003).....35

Mars Inc. v. JCM Am. Corp.,
No. 05-cv-3165, 2006 WL 1704469 (D.N.J. 2006) 26

Matrixx Initiatives, Inc. v. Siracusano,
131 S. Ct. 1309 (2011) 1, 13

McHenry v. Renne,
84 F.3d 1172 (9th Cir. 1996) 13

Mosaid Techs. Inc. v. Samsung Elecs. Co.,
362 F. Supp. 2d 526 (D.N.J. 2005) 15

Nationwide Mut. Ins. Co. v. Garzone,
No. 07-cv-4767, 2009 WL 2996468 (E.D. Pa. 2009) 38

In re Neurontin Antitrust Litig.,
No. 02-cv-1390, 2009 WL 2751029 (D.N.J. 2009) 35

Nomadix, Inc. v. Hosp. Core Servs. LLC,
No. 14-cv-08256, 2015 WL 3948804 (C.D. Cal. 2015) 33

One Lot Emerald Cut Stones v. United States,
409 U.S. 232 (1972) 21

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005) (en banc) 28

Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.,
324 U.S. 806 (1945) 17

Primetime 24 Joint Venture v. Nat'l Broad. Co.,
219 F.3d 92 (2d Cir. 2000) 36

Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.,
508 U.S. 49 (1993) 36

Purolite Int'l, Ltd. v. Rohm & Haas Co.,
No. 91-cv-2740, 1992 WL 142018 (E.D. Pa. 1992) 17

Refac Int'l, Ltd. v. Lotus Dev. Corp.,
81 F.3d 1576 (Fed. Cir. 1996) 24

Regeneron Pharms., Inc. v. Merus N.V.,
864 F.3d 1343 (Fed. Cir. 2017) 17

Renfro v. Unisys Corp.,
671 F.3d 314 (3d Cir. 2011) 1, 13

Rohm & Haas Co. v. Brotech Corp.,
770 F. Supp. 928 (D. Del. 1991).....16, 17

Rohm & Haas Co. v. Crystal Chem. Co.,
722 F.2d 1556 (Fed. Cir. 1983).....23, 24

Sanders v. The Mosaic Co.,
418 F. App'x 914 (Fed. Cir. 2011).....18, 21

Skinner v. Switzer,
131 S. Ct. 1289 (2011).....1, 13

In re Theodor Groz & Sohne,
972 F.2d 1352 (Fed. Cir. 1992).....38

Therasense, Inc. v. Becton, Dickinson & Co.,
649 F.3d 1276 (Fed. Cir. 2011) (en banc).....2, 17, 20, 24, 31

Toledo Mack Sales & Serv., Inc. v. Mack Trucks, Inc.,
530 F.3d 204 (3d Cir. 2008).....35

Transclean Corp. v. Bridgewood Servs., Inc.,
77 F. Supp. 2d 1045 (D. Minn. 1999).....29

U.S. Aluminum Corp./Texas v. Alumax, Inc.,
831 F.2d 878 (9th Cir. 1987).....21

United States v. Am. Bell Tel. Co.,
128 U.S. 315 (1888).....18

United States v. One Assortment of 89 Firearms,
465 U.S. 354 (1984).....21

USS-POSCO Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council,
31 F.3d 800 (9th Cir. 1994).....36, 37

Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.,
382 U.S. 172 (1965).....34

Waugh Chapel S., LLC v. United Food & Commercial Workers Union Local 27,
728 F.3d 354 (4th Cir. 2013).....36, 37

In re Wellbutrin XL Antitrust Litigation Indirect Purchaser Class,
868 F.3d 132 (3d Cir. 2017).....36, 37

Statutes

New Jersey Antitrust Act.....38

Sherman Act.....34, 38

Rules

Fed. R. Civ. P. 12.....13

Fed. R. Civ. P. 13.....15, 16, 17

Other Authorities

37 C.F.R. § 42.100(b).....28

18 Charles Alan Wright et al.,
Federal Practice and Procedure § 4422 (3d ed. 2018).....21

Manual of Patent Examining Procedure ("MPEP").....33, 34

TABLE OF ABBREVIATIONS

Abbreviation	Meaning
207 Dkt. [docket number] at [pincite]	Docket entry and pin citation in *Allergan Sales, LLC v. Sandoz Inc.*, No. 2:12-cv-207 (E.D. Tex. filed Apr. 13, 2012)
'453 patent	U.S. Patent No. 9,770,453 (Ex. 1)
'801 patent	U.S. Patent No. 9,907,801 (Ex. 2)
'802 patent	U.S. Patent No. 9,907,802 (Ex. 3)
'463 patent	U.S. Patent No. 7,323,463 (Ex. 4)
'149 patent	U.S. Patent No. 7,030,149 (Ex. 5)
'976 patent	U.S. Patent No. 7,320,976 (Ex. 6)
'258 patent	U.S. Patent No. 7,642,258 (Ex. 7)
'409 patent	U.S. Patent No. 8,354,409 (Ex. 8)
'890 patent	U.S. Patent No. 8,133,890 (Ex. 9)
'425 patent	U.S. Patent No. 8,748,425 (Ex. 10)
'751 patent	U.S. Patent No. 9,474,751 (Ex. 11)
Asserted Patents	'453, '801, and '802 patents
BID	Twice per day
FDA	U.S. Food & Drug Administration
NDA	New Drug Application
PTO	U.S. Patent & Trademark Office
TID	Three times per day

INTRODUCTION

Allergan seeks to short-circuit Sandoz's counterclaims at the pleadings stage, but its arguments read as if made after trial or on summary judgment. That compels denial of Allergan's motion. At this early stage, Sandoz need not show that it "'will ultimately prevail'"; it is sufficient that it "allege 'enough facts to state a claim to relief that is plausible on its face.'" *Renfro v. Unisys Corp.*, 671 F.3d 314, 320-21 (3d Cir. 2011) (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1322 n.12 (2011); *Skinner v. Switzer*, 131 S. Ct. 1289, 1296 (2011)). Sandoz has done that and more. Allergan acknowledges the painstaking detail of Sandoz's counterclaims, counting at least 30 transgressions in Sandoz's allegations. *See* Allergan MTD at 12-15.[1] The Federal Circuit and district courts nationwide have found inequitable conduct adequately alleged on far less. The same goes for Allergan's antitrust counterclaims under Third Circuit law. Sandoz will ultimately prevail on the merits, but need not prove that now.

Tellingly, Allergan does not lead with an argument on the merits. Instead, it contends Sandoz's counterclaims were compulsory in earlier cases, so cannot be asserted here. Allergan's argument is logically and legally unsound. Several of Sandoz's counterclaims seek unenforceability judgments *only* as to the three patents ***asserted here for the first time***. Two of those patents issued after Allergan filed its initial complaint in this case, and the third issued after the district court entered final judgment in the previous case. It is thus "obvious" that Sandoz's counterclaims as to those patents could not have been compulsory before, since "there [was not] in existence a cause of action by the plaintiff to which the compulsory counterclaim could [have been] filed." *See Dow Chem. Co. v. Melton Corp.*, 281 F.2d 292, 297 (4th Cir. 1960). Even as to Sandoz's counterclaims that seek unenforceability judgments against the earlier-asserted patents,

[1] Citations to "Allergan MTD" refer to Allergan's Motion to Dismiss, Dkt. 112.

Sandoz argues that the combined evidence of Allergan's continuing, decades-long pattern of deceiving the Patent Office—including evidence that did not exist when the earlier suits were being litigated—infects every member of the Combigan-patent family. That plausible allegation is more than sufficient to defeat Allergan's motion at this early stage.

Allergan's motion also fails on the merits. On inequitable conduct, Allergan relies on other courts' findings on other issues to argue that Allergan's omissions and falsifications to the Patent Office were immaterial. But Allergan's focus on what ***courts*** may have found (on different issues) confuses the inquiry. As the Federal Circuit has made clear, the inequitable conduct inquiry asks whether the ***Patent Office*** would have rejected a patent's claims if the applicant had presented the deliberately withheld information. That distinction—court versus PTO—makes a world of difference. The PTO gives patent claims their *broadest reasonable construction* and rejects them if a *preponderance of evidence* shows they are unpatentable. Applying those standards, the PTO is much more likely to find a claim unpatentable than is a federal court—which more narrowly construes claims to have their *ordinary meaning to a skilled artisan*, and can invalidate claims only on *clear and convincing evidence*. Thus, "even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked issuance under the PTO's different evidentiary standards." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc)). Allergan's heavy reliance on other ***courts'*** findings on issues ***other than inequitable conduct*** is entirely misplaced and cannot show Sandoz's allegations lack plausible merit.

And meritorious they are. Before Allergan filed a single Combigan-family patent, it knew that "[n]o patent protection [was] available" on the Combigan formulation. (¶ 37);[2] Ex.

[2] Unless otherwise indicated, citations to (¶ #) refer to Sandoz's Counterclaims, Dkt. 73.

37, *207* Dkt. 343, 10/26 PM Tr. (Gryziewicz) at 41:21-42:2, 42:15-19. Allergan nonetheless applied for several patents (11 and counting) covering Combigan and related treatment methods. Along the way, Allergan knowingly provided false affidavits to and withheld material information from the PTO. For example, Allergan's VP of Ophthalmology declared that "***0.0%***" of Combigan patients "experienc[ed] adverse events of the nervous system"—even though Allergan had clinical-study data showing otherwise. (¶ 212). Allergan told the PTO that Combigan performed at least as well as brimonidine, even though its own expert concluded that "[i]n ocular hypertension patients, the mean IOP reductions from baseline were greater in the Brimonidine group than in the [Combigan] group at hour 9 at all follow-up visits." (¶ 119); Ex. 35, *207* Dkt. 341, 10/25 PM Tr. (Noecker) at 104:22–105:3. And Allergan kept from the Patent Office several FDA criticisms of its clinical-study methods and results. Allergan later submitted *some* of that information, but only buried in a mass of 200+ other references. Sandoz has more than plausibly alleged that Allergan's continuing pattern of concealment and misrepresentation shows a specific intent to deceive.

Sandoz's antitrust counterclaims are equally plausible, and Allergan's arguments again miss the mark. Allergan wrongly asserts that all of Sandoz's antitrust counterclaims require showing "sham litigation," but that is simply not true—only one of its three federal claims does. And, even as to that one, Allergan incorrectly argues it should be dismissed if any one of the earlier litigations was not "objectively baseless." Under Third Circuit law, however, the "objectively baseless" standard does not apply here, much less on a per-litigation basis. The relevant question is whether Allergan's *serial litigations as a whole* are anti-competitive. Sandoz has adequately pleaded that they are. Allergan's motion to dismiss should be denied in full.

BACKGROUND

Allergan markets Combigan as a brand of eye drops for reducing intraocular pressure ("IOP") in patients suffering from glaucoma or ocular hypertension. Allergan MTD at 3. The Combigan composition contains 0.2% brimonidine tartrate and 0.68% timolol maleate in a single bottle. (¶ 2). The FDA approved BID (*i.e.*, twice-daily) timolol maleate for treating elevated IOP in 1978 (brand name, Timoptic), and approved TID (*i.e.*, thrice-daily) brimonidine tartrate for treating elevated IOP in 1996 (brand name, Alphagan). (¶¶ 20-21).

Although the FDA has only approved Alphagan for thrice-daily use, since the 1990s doctors have prescribed the twice-daily administration of Alphagan and Timoptic—the two drugs being administered from separate bottles. (¶¶ 20, 22, 25); Ex. 35, *207* Dkt. 341, 10/25 PM Tr. (Tanna) at 154:7–16; Ex. 38, *207* Dkt. 344, 10/27 Tr. (Noecker) at 21:12–22:2; Ex. 35, *207* Dkt. 341, 10/25 PM Tr. (Tanna) at 152:5–12; Ex. 36, *207* Dkt. 342, 10/26 AM Tr. (Samples) at 96:12–16; Ex. 38, *207* Dkt. 344, 10/27 Tr. (Noecker) at 22:13–16. Also, in 1995, Allergan itself conducted clinical studies on twice-daily brimonidine, and argued to the FDA that BID brimonidine was clinically equivalent to TID brimonidine. (¶ 21); Ex. 18, Alphagan Final Study Report at 12. As part of those studies, Allergan unsurprisingly learned that patients taking twice-daily brimonidine showed a lower incidence of side effects than those taking thrice-daily brimonidine. For example, twice-daily brimonidine resulted in half the incidence of somnolence (sleepiness) as did thrice-daily brimonidine. (¶¶ 108-110); Ex. 18, Alphagan Final Study Report at Table 19. Alphagan had also previously been approved for twice-daily dosing in other countries. (¶ 23); Ex. 38, *207* Dkt. 344, 10/27 Tr. (Noecker) at 17:23–25; Ex. 26, David, R., Brimonidine (Alphagan®): A clinical profile four years after launch, Eur. J. Ophthal., 11 Suppl 2:S72–7 (July 2001) ("David").

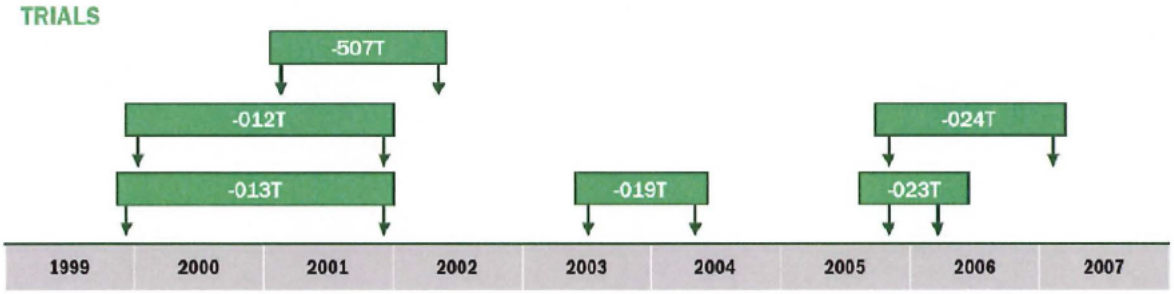
Although Alphagan and Timoptic were often prescribed and administered together, compliance suffered when patients had to take the two drugs from separate bottles. (¶ 36); Ex. 36, *207* Dkt. 342, 10/26 AM Tr. (Schiffman) at 83:20–84:1. Allergan thus recognized the obvious benefits to patient compliance of combining the two drugs in one bottle. (¶ 36); Ex. 34, *207* Dkt. 340, 10/25 AM Tr. (Batoosingh) at 62:15–21; *see* Ex. 36, *207* Dkt. 342, 10/26 AM Tr. (Schiffman) at 83:20–84:1. Indeed, in internal documents, Allergan recognized that "[n]o patent protection [was] available on [a] combination product." (¶ 37); Ex. 37, *207* Dkt. 343, 10/26 PM Tr. (Gryziewicz) at 41:21–42:2, 42:15–19. And as the Federal Circuit has already concluded, claims to the fixed combination of brimonidine and timolol—Combigan—were obvious. (¶ 407); *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1293 (Fed. Cir. 2013). Still, Allergan has filed at least eleven patent applications directed to that fixed combination and related methods of treatment. (¶ 32); *see* U.S. Pat. Nos. 7,030,149, 7,323,463, 8,133,890, 8,354,409, 8,748,425, 9,770,453, 9,907,801, 9,907,802, 7,320,976, 7,642,258, and 9,474,751. *See supra* Table of Abbreviations (for exhibit numbers). For the past decade and across four lawsuits, Allergan has asserted ten of the patents in that family against Sandoz in an effort to stop generic competition.

Allergan filed the first application in the Combigan patent family over fifteen years ago. (¶ 33); Ex. 5, ('149 patent, cover) (filed as U.S. Patent Application No. 10/126,790 in April 2002). Recognizing the *prima facie* obviousness of its claimed "inventions," Allergan presented the Patent Office with cherry-picked data from various clinical trials as alleged evidence that Allergan's claimed compositions and methods achieved unexpected results. (¶¶ 331–351). Nearly all of the clinical studies Allergan relied on during prosecution had finished when the first patent in the Combigan family issued (the '149 patent), and all had finished when the second patent issued (the '463 patent). (¶¶ 39, 41, 42, 67, 69–72, 77, 79–82, 86, 88–91, 95, 97–100);

Exs. 21-25, NDA 21-398, Medical Review, Statistical Review, Summary Review (collectively, the "Combigan Medical Review"); Ex. 12, PTX 13A (4/15/02 12-Month Report 012T study); Ex. 13, PTX 13B (5/14/02 12-Month Report 013T study); Ex. 20, DTX 1400 (12/3/03 Report 507T study) at 11; Ex. 14, PTX 13C (8/9/04 Report 019T study) at 4; Ex. 15, PTX 13D (6/24/06 Report 023T study) at 3; Ex. 16, PTX 13E (4/27/07 Report 024T study) at 3.

A. Allergan's Clinical Studies

The so-called 012T and 013T studies were among the earliest Phase III clinical trials that Allergan performed on Combigan. Allergan conducted those two studies well before filing the application for the '149 patent on April 19, 2002. Ex. 5 (cover). The timeline below depicts the start and end dates of those and other studies that Allergan conducted on Combigan. *See id.*



The 012T and 013T studies compared a fixed composition of brimonidine and timolol BID (*i.e.*, Combigan) to brimonidine alone TID (*i.e.*, Alphagan, as approved by the FDA). (¶ 42). The data from the 012T study was less favorable for Allergan's arguments to the PTO than was the data from the 013T study; indeed, for some side effects, the 012T study showed that Combigan performed ***worse than brimonidine monotherapy***. (¶ 44); *compare* Ex. 17, PTX 13L at 6, *with* Ex. 13, PTX 13B at 7. For example, with respect to somnolence—an adverse event that Allergan told the Patent Office Combigan unexpectedly reduced—the 012T study showed an incidence for Combigan ***more than double*** that reported in the 013T study. (¶ 48). Thus, Allergan chose to include data from the 013T study, *but not* the 012T study, in its patents'

specifications. (¶¶ 43, 46). In particular, the specifications of Allergan's Combigan-family patents include a table from the 013T study that compares the incidences of adverse events for Combigan BID to the incidences for brimonidine TID and, separately, the incidences for timolol BID. *See* Ex. 5, '149 Patent at col. 7. Allergan's omission of the 012T study from the patents' specifications hid the full story of Combigan's clinical results from the PTO.

But it gets worse. Even the data from the 013T study that Allergan provided does not tell the full story. Allergan presented data only from the first three months of the year-long 013T study, *omitting* the remaining nine months. *Id.* But, for most side effects, the 12-month study showed ***worse*** results than the 3-month study. (¶¶ 43-44); *compare* Ex. 13, PTX 013B at 7 (12-month study), *with* Ex. 17, PTX 013L at 6 (3-month study). The 12-month study also showed worse results with respect to efficacy. After reviewing the 12-month data, the FDA concluded that "[n]either [the 012T or 013T] study … demonstrate[d]" that Combigan BID made "a clinically significant contribution" to lowering IOP compared to Alphagan (brimonidine) TID. (¶¶ 59–61); *see also* Ex. 21, Medical Review, Part I at 78-79; Ex. 24, Statistical Review at 15. Allergan did not initially provide that data to the PTO, and never told the PTO that the FDA had criticized its data as insufficient. (¶¶ 42–48, 52–61).

Shortly after it completed the 012T and 013T studies, Allergan conducted the 507T study, which compared Combigan to the closest prior-art regimen: "concomitant" administration of brimonidine BID and, from a separate bottle, timolol, BID—a regimen that doctors in the United States regularly prescribed. (¶¶ 67–72); *see* Ex. 20, DTX 1400. The only difference between the regimen studied in the 507T study and Combigan was whether the brimonidine and timolol drugs were combined in a single bottle (Combigan) or not (507T study). (¶ 67). F.J. Goni published the results of the 507T study in 2005, comparing the side-effect profiles of Combigan and the

concomitant regimen. (¶¶ 49–51, 73); Ex. 19, DTX 1209 at 586 (Table II).[3] Those results showed Combigan performed far ***worse*** than the concomitant regimen for several adverse events, including nervous system adverse events. (¶¶ 49–51). Allergan, including its Vice President of Ophthalmology, Dr. Rhett Schiffman, knew of these results. Ex. 41, AGN_COM00671353.[4] But Allergan did not submit the data from the 507T study until after the '890 patent's application was filed, and did not submit drafts of the Goni article as early as it could have. (¶¶ 49–51, 73–78).[5]

Nearly one year after the 507T study ended, Allergan conducted the four-week 019T study. (¶¶ 77–85); Ex. 14, PTX 13C. Unlike the 507T study, the 019T study did ***not*** compare Combigan to concomitant administration of brimonidine and timolol, but instead to brimonidine TID, or to brimonidine TID and timolol BID. (¶ 77); Ex. 14, PTX 13C (8/9/04 Report 019T study) at 4. At the study's end, the FDA concluded that Allergan had "fail[ed] to demonstrate that the efficacy of the combination product is equivalent to the efficacy attained when each of the individual components are dosed concurrently." (¶ 84); Ex. 22, Medical Review, Part II at 38, 52. The FDA also found that the 019T study was "not sufficient to determine the adverse event profile [of Combigan] due to the [study's] short duration." (¶ 84); Ex. 22, Medical Review, Part II at 52. Allergan never submitted these FDA criticisms to the Patent Office.

---

[3] Exhibits 19, 33, and 39–42 to this brief were not cited in Sandoz's Amended Answer and Counterclaims. The Court need not rely on these exhibits to deny Allergan's motion to dismiss. Sandoz cites them merely as examples of additional evidence that it has gathered during discovery (and expects to continue gathering) as support for its counterclaim allegations.

[4] *See supra* note 3.

[5] To be clear, the '149 patent cites Goni in a list of "Other Publications" considered. Ex. 5 (cover). But just because Allergan eventually submitted Goni does not mean that it lacked the specific intent to deceive the PTO when it initially withheld that reference, nor does it mean that Allergan's ultimate submission was sufficient to cure its original omission.

Beginning in late 2005, Allergan conducted two more clinical studies: the 023T and 024T studies. (¶¶ 86–102); Ex. 15, PTX 13D (6/24/06 Report 023T study); Ex. 16, PTX 13E (4/27/07 Report 024T study) at 2. The 023T study, which lasted only 10 days, compared Combigan to serial administration of brimonidine TID and timolol BID in healthy patients. The FDA concluded that Combigan's "numerical" superiority over the serial regimen with respect to oral dryness was insufficient to offset Combigan's lower efficacy in reducing IOP. (¶¶ 92–94); Ex. 21, Medical Review, Part I at 77. The FDA also recommended that Allergan consider the effect of patient age on adverse events. (¶ 94); Ex. 22, Medical Review, Part II at 10. In the follow-on 024T study, Allergan collected data that showed a decreased incidence of somnolence in patients ***over age 40***.[6] (¶ 271 n.16); Ex. 16, PTX 13E. The FDA approved Combigan based on that data, but cautioned that the 024T study's 10-day duration may have been too short to provide meaningful safety information. (¶¶ 101–102); Ex. 24, Statistical Review at 5–6.

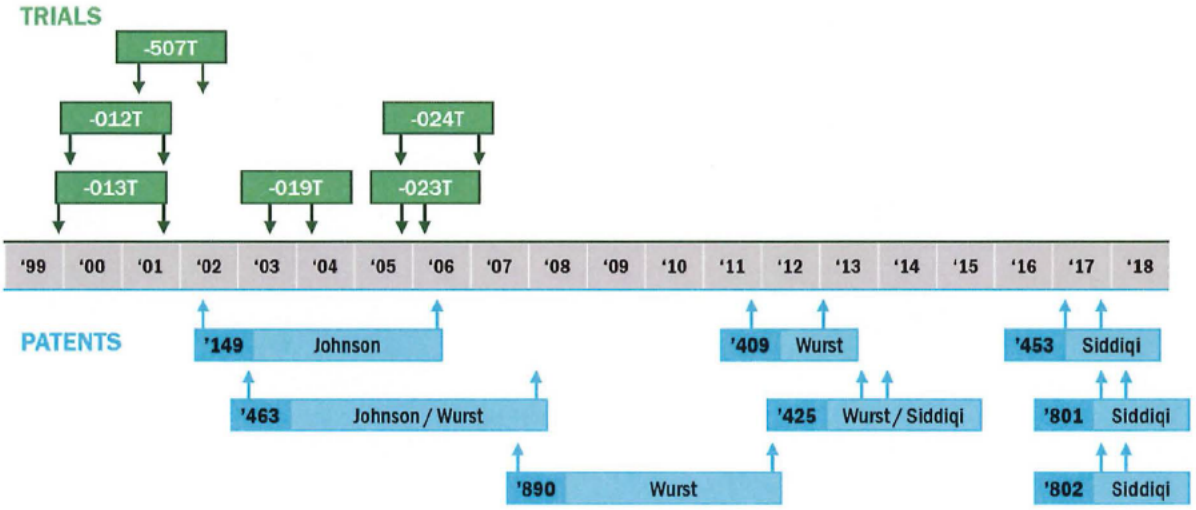
B. Allergan's Prosecution of the Combigan-Family Patents

Allergan's prosecution of the Combigan-family patents began over 16 years ago and continues to this day. Eight of the resulting patents—the '149, '463, '890, '409, '425, '453, '801 and '802 patents—are particularly relevant here, and three Allergan attorneys figured most prominently in their prosecution: Brent Johnson ('149 and '463 patents); John Wurst ('463, '890, '409, and '425 patents); and Lorenz Siddiqi ('453, '801, and '802 patents, asserted here). The clinical studies described above were central to Allergan's arguments to the Patent Office that the claims in its Combigan-family patent applications were patentable. Indeed, after the Examiner initially "held that a *prima facie* case of obviousness had been made against" the '149 patent's

[6] This fact, one of the many that Allergan attorneys deliberately withheld from the Patent Office, was material to the patentability of Allergan's claims because it is undisputed that none of Allergan's patents recite methods for treating only patients older than 40. (¶¶ 170 n.3, 271 n.16).

claims, Allergan made "no further attempt . . . to argue" otherwise. Ex. 27 at 3. Instead, Allergan submitted an affidavit "which [purportedly] show[ed] unexpected results." *Id.*; *see* (¶ 186). But Allergan always compared Combigan to distant prior art—brimonidine TID—instead of the closest prior art—serial, BID dosing of brimonidine and timolol. (¶¶ 185–210).[7]

The timeline below shows when the patents' applications were pending before the Patent Office; who prosecuted them; that Allergan had conducted several clinical trials before filing the first Combigan-family patent application; and that it had completed several more before prosecuting the applications leading to the Asserted Patents. As noted, Allergan disclosed only a subset of those studies' results to the Patent Office, and disclosed *none* of the FDA's criticisms.



While prosecuting the '149 patent, for example, Dr. Johnson submitted a declaration from Dr. Rhett Schiffman, an Allergan executive, stating that the "percentage of patients in the Combination [*i.e.*, Combigan ***BID***] group experiencing adverse events of the nervous system"

[7] There should be no dispute that serial, BID dosing of brimonidine and timolol is the closest prior art to the claimed regimen, and that brimonidine alone TID is not. There is only one difference between the claimed regimen and serial, BID dosing of brimonidine and timolol: the latter involves administering the two drugs from ***separate*** bottles, whereas the former involves administering them from the ***same*** bottle. In contrast, the brimonidine alone TID regimen differs from the claimed regimen both in terms of frequency (TID vs. BID) and active ingredients (no timolol is administered in the brimonidine-alone regimen).

was unexpectedly "0.0%." Ex. 27 ('149 Patent File History, July 27, 2004 Amendment and Declaration). That declaration presented data only from the 019T study. Ex. 33, Schiffman Dep. Tr. at 196:2–24.[8] Dr. Johnson and Dr. Schiffman omitted, however, that the FDA found that the 019T study's data was wholly insufficient to show that Combigan was as effective as serial brimonidine and timolol, or "to determine the adverse event profile [of Combigan] due to the [study's] short duration." Ex. 22, Medical Review, Part II at 52. Nor did Drs. Johnson or Schiffman disclose the material fact that the already-conducted 507T study plainly showed that Combigan *did* cause nervous-system side effects. Ex. 19, DTX 1209 at 586 (Table II).

More than a year after submitting Dr. Schiffman's declaration, Dr. Johnson admitted to the Patent Office, for the first time, that "another clinical trial [the 507T trial]," performed ***by Allergan***, "had been carried out where some nervous system adverse events were observed." Ex. 28 ('149 Patent File History, Aug. 24, 2005 Amendment); (¶ 218). According to Dr. Johnson, even though the Schiffman declaration was false, "the frequency of nervous system adverse events [for Combigan] was still significantly less" than the concomitant therapy of brimonidine ***TID*** and timolol ***BID***. *Id.* That statement, which continued to suggest unexpected results, misrepresented Allergan's knowledge for at least four reasons.

First, the fact that reducing the frequency of brimonidine administration from ***TID*** to ***BID*** correlated with fewer side effects without a significant loss of efficacy was *not* unexpected when Allergan filed the '149 patent's application. *See*, *e.g.*, (¶¶ 182–210). Allergan had known since a study ***it conducted in 1992*** that brimonidine TID offered "no clinically significant advantage" over brimonidine BID, and that the incidence of somnolence in the TID regimen (3.9%) was nearly twice that of the BID regimen (2.0%). *See* (¶¶ 103–112); Ex. 18, PTX 291 at

[8] *See supra* note 3.

12, 74 (Table 19). ***Second***, the 012T study—which Dr. Johnson withheld from the Patent Office—showed that Combigan had a higher incidence of nervous-system side effects (like somnolence) than did brimonidine ***TID***. (¶¶ 110, 331–351); Ex. 23, Medical Review, Part III at 20, 33. ***Third***, Dr. Johnson withheld that the 507T study showed Combigan had a significantly higher incidence of somnolence than did concomitant brimonidine ***BID*** and timolol ***BID***. (¶ 222); Ex. 19, DTX 1209 at 586 (Table II). ***Last***, Dr. Johnson never disclosed the FDA's fundamental criticisms of the data he actually presented, *e.g.*, from the 012T, 013T, and 019T studies. *See*, *e.g.*, (¶¶ 59–61, 79–85, 333).

When Mr. Wurst took over prosecution of the Combigan patent family, he continued Dr. Johnson's practice of selective disclosure. (¶ 139). In prosecuting the '890 patent, for example, Mr. Wurst repeatedly argued that the 013T study results in the specification showed that, compared to "brimonidine monotherapy," the pending claims showed "improvement in reducing adverse effect[s]," including "foreign body sensation" and "conjunctival hyperemia." *See* (¶¶ 169–172); Ex. 29 ('890 Patent File History, Sept. 11, 2009 Examiner Interview Summary). But Mr. Wurst did not disclose the results of the 012T study, which showed Combigan had ***higher*** incidences of at least conjunctival hyperemia and foreign body sensation. *See* (¶¶ 110, 309, 331–351); *compare* Ex. 17, PTX 13L at 6, *with* Ex. 12, PTX 13A at 7, Ex. 13, PTX 13B at 7, Ex. 23, Medical Review, Part III at 20–21 (Table 9).

When the third attorney, Mr. Siddiqi, took over prosecution of the Asserted Patents, he failed to rectify his predecessors' omissions and misrepresentations. (¶ 146). Instead, Mr. Siddiqi buried some of the omitted references in a barrage of 200+ marginally relevant (at best) documents. *See* (¶¶ 352–369); Ex. 32 ('802 patent file wrapper, Information Disclosure Statement) (Nov. 9, 2017). Even then, Mr. Siddiqi omitted information contradicting the

existence of unexpected results, including a report from one of Allergan's litigation experts, Dr. Mei Sheng Duh, explaining that some Allergan clinical studies showed that "[i]n ocular hypertension patients, the mean IOP reductions from baseline were greater in the brimonidine [***TID***] group than in the combination [*i.e.*, Combigan ***BID***] group at" certain time points. (¶¶ 250–265); Ex. 35, *207* Dkt. 341, 10/25 PM Tr. (Noecker) at 104:22–105:5; Ex. 39, Siddiqi Dep. Tr. at 252:5–24.[9] As with the above examples and others pervading its 16 years of prosecution, Allergan should have presented that information. It never did.

ARGUMENT

To survive a motion to dismiss, a complainant "need only allege 'enough facts to state a claim to relief that is plausible on its face.'" *Renfro*, 671 F.3d at 321 (quoting *Matrixx Initiatives*, 131 S. Ct. at 1322 n.12). Thus, when deciding a motion to dismiss under Rule 12(b)(6), "[t]he question is 'not whether [a party] will ultimately prevail . . . but whether [its] complaint [is] sufficient to cross the federal court's threshold.'" *Id.* at 320 (quoting *Skinner*, 131 S. Ct. at 1296). To answer that question, "courts must 'accept all factual allegations as true, construe the [claims] in the light most favorable to the [complainant], and determine whether, under any reasonable reading of the [claims], the [complainant] may be entitled to relief.'" *Bruni v. City of Pittsburgh*, 824 F.3d 353, 360 (3d Cir. 2016) (quoting *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009)); *Indus. Tech. Research Inst. v. LG Corp.*, No. 12-cv-929, 2012 WL 4469383, at *2 (D.N.J. 2012). The party moving to dismiss has "'the burden of showing that no claim has been presented.'" *Bruni*, 824 F.3d at 361 n.11 (quoting *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005)). Allergan cannot meet its burden here. Its motion should be denied.[10]

---

[9] *See supra* note 3.

[10] Allergan accuses Sandoz's pleadings of containing "vague and sweeping allegations," and argues that the Court could "strike the entire pleading" on this basis. Allergan MTD at 3 n. 2

I. SANDOZ'S INEQUITABLE CONDUCT AND ANTITRUST COUNTERCLAIMS ARE NOT COMPULSORY COUNTERCLAIMS THAT COULD HAVE BEEN RAISED IN PRIOR LITIGATIONS

Allergan's lead argument is that Sandoz's inequitable conduct and *Walker Process* claims were compulsory in earlier cases, and that Sandoz thus cannot raise those claims in this case. Allergan MTD at 18–22. Allergan's arguments are meritless. Some of Sandoz's counterclaims allege that the '453, '801, and '802 patents are unenforceable for inequitable conduct. (¶¶ 31–40 (pp. 177–178)). None of these three patents was asserted in the previous litigations between the parties. Indeed, the '801 and '802 patents issued ***after the initial complaint was filed in this case***. Allergan MTD at 11. And the '453 patent issued after the district court entered final judgment in the last suit between the parties. *Compare* Ex. 1 at 1 ('453 patent issuing Sept. 26, 2017), *with 207* Dkt. 353 (final judgment issuing Jan. 9, 2017).

Because none of the patents asserted here was asserted in an earlier suit, it should go without saying that Sandoz never before had an *opportunity*, much less an *obligation*, to assert any counterclaims of unenforceability against them. In patent-infringement suits, "[e]ach patent asserted raises an independent and distinct cause of action." *Kearns v. Gen. Motors Corp.*, 94 F.3d 1553, 1555 (Fed. Cir. 1996). And for a counterclaim to have been compulsory in an earlier case, "it is obvious that there must [have been] in existence a cause of action by the plaintiff to which the compulsory counterclaim could [have been] filed." *Dow Chem.*, 281 F.2d at 297. Thus, in *Dow Chemical*, the Fourth Circuit concluded that a defendant accused of infringing one

---

(citing Fed. R. Civ. P. 12(e); *McHenry v. Renne*, 84 F.3d 1172, 1177–78 (9th Cir. 1996)). But Sandoz's pleadings are far from vague or general. They identify specific conduct (Allergan counts over 30 "overt acts"), including the who, what, where, when, why, and how of each alleged basis of inequitable conduct. *McHenry*—a non-patent case in which the pleading contained lengthy but irrelevant information—is inapposite. Here, Sandoz has laid out the predicate facts for each basis of inequitable conduct that it has identified. The length of Sandoz's counterclaims is a direct result of the extensive series of omissions and misrepresentations Allergan made during prosecution spanning over a decade.

patent in an earlier suit was not barred from seeking declaratory judgments of invalidity and non-infringement with respect to another patent in a later suit, since the second patent had not been adjudicated before. *Id.* at 296–97. The result should be no different here.

Allergan nonetheless argues that, to succeed on its inequitable conduct claims as to the patents asserted in this case, Sandoz "must show inequitable conduct of the patents that were already litigated in the earlier suits." Allergan MTD at 19. Even if true, that has nothing to do with whether Sandoz can challenge the enforceability of the patents newly asserted in this case. In several of its counterclaims, Sandoz seeks judgments of unenforceability ***only*** for the asserted '453, '801, and '801 patents—***not*** for other patents in the Combigan-patent family. (¶¶ 31–40 (pp. 177–178)). Thus, even if Sandoz must show that a court ***would have*** found that the earlier-asserted Combigan-family patents were unenforceable to prevail on its inequitable conduct claims for the Asserted Patents, that does ***not*** mean that this Court must enter judgments of unenforceability with respect to the earlier-asserted patents. Thus, whether Rule 13 bars Sandoz from seeking judgments that the earlier-asserted patents themselves are unenforceable for inequitable conduct is irrelevant as to whether Sandoz can seek such a judgment with respect to the patents asserted ***for the first time*** in this case, including by reliance, in part, on inequitable conduct regarding the earlier patents. Allergan points to no precedent holding otherwise.

Allergan's compulsory-counterclaim arguments also fail for a separate and independent reason, which applies to all of Sandoz's inequitable conduct counterclaims. As Allergan recognizes, to prove that a patent is unenforceable under a theory of "infectious inequitable conduct," Sandoz will rely on Allergan's actions in prosecuting all of the "related patents" in the Combigan-family of patents, which undisputedly "bear an immediate and necessary relation to" each other. Allergan MTD at 19 (quoting *Mosaid Techs. Inc. v. Samsung Elecs. Co.*, 362 F. Supp.

2d 526, 553-54 (D.N.J. 2005)). Under Sandoz's theory of "infectious inequitable conduct," the totality of Allergan's 16 years of prosecution misconduct is alleged to show a specific intent to deceive the Patent Office. (¶¶ 16, 38, 199, 236, 257, 284, 300, 320, 341, 362, 375, 424). In the earlier litigations between the parties, many of the continued omissions and misrepresentations that Allergan made in prosecuting the Asserted Patents simply had not yet happened and thus could not have been used to support Sandoz's current inequitable conduct counterclaims. Thus, the fact that Sandoz's counterclaims do not "arise[] out of the [same] transaction or occurrence that" existed in the earlier suits is an independent reason why Allergan is not barred from asserting its inequitable conduct counterclaims in this case. Fed. R. Civ. P. 13(a)(1)(A).

None of the decisions that Allergan cites as purported support for its argument are to the contrary. Unlike this case, none of those cases involved claims of infectious inequitable conduct. Indeed, only three of the decisions that Allergan cites (none of which bind this Court) address whether inequitable conduct or *Walker Process* counterclaims are compulsory in a patent-infringement case. Allergan MTD at 19–22 (citing *Goodman Mfg. Co. v. Carrier Corp.*, No. 13-cv-2014, 2014 WL 4954281 (D. Del. 2014); *Rohm & Haas Co. v. Brotech Corp.*, 770 F. Supp. 928 (D. Del. 1991); *Am. Packaging Corp. v. Golden Valley Microwave Foods, Inc.*, No. 94-cv-1839, 1995 WL 262522 (E.D. Pa. 1995)).

Each of those three cases materially differs from this one. In *Goodman* and *American Packaging*, the district courts concluded that accused infringers who failed to raise antitrust or inequitable conduct counterclaims against patents asserted in earlier infringement suits were barred from seeking declaratory judgments of inequitable conduct and antitrust violations in later suits involving ***the same patents***—unlike here, in which Allergan asserts infringement of three never-before-litigated patents. *Goodman*, 2014 WL 4954281, at *1–2; *Am. Packaging*, 1995 WL

262522, at *1–3, *6. And, in *Rohm & Haas*, the court "expressly decline[d] to decide the issue of whether [the defendant] ha[d] properly asserted a counterclaim in th[e] action alleging inequitable conduct." 770 F. Supp. at 933 n.1. Moreover, each of the patents at issue in the later-filed case in *Rohm & Haas* had issued ***before*** the complaint was filed in the earlier-filed case. *Compare*, *Rohm & Haas*, No. 1:90-cv-109, Dkt. No. 1 (complaint in earlier-filed case filed Mar. 1, 1990), *with Purolite Int'l, Ltd. v. Rohm & Haas Co.*, No. 91-cv-2740, 1992 WL 142018, at *1–2 (E.D. Pa. 1992) (listing patents at issue in later-filed case, all of which issued before Mar. 1, 1990). That starkly contrasts with this case. While the defendant in *Rohm & Haas* could have asserted inequitable conduct counterclaims in the first suit against the patents at issue in the second suit, Sandoz plainly could not have done that here—*none of the Asserted Patents in this case had issued before the earlier litigations were filed*.

Try as it might, Allergan cannot distort Rule 13 to serve its misconceived efforts to cut-off Sandoz's inequitable conduct and antitrust counterclaims at the threshold. Sandoz could not have raised its current counterclaims in the earlier litigations, and it has more than adequately alleged them in this one. Allergan has not met its high burden to prove otherwise.

II. SANDOZ'S INEQUITABLE CONDUCT CLAIMS ARE PLAUSIBLE

"The far-reaching social and economic consequences of a patent . . . give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). The Supreme Court and Federal Circuit have thus developed "'[i]nequitable conduct [as] an equitable defense to patent infringement that, if proved, bars enforcement of a patent.'" *Regeneron Pharms., Inc. v. Merus N.V.*, 864 F.3d 1343, 1350 (Fed. Cir. 2017) (quoting *Therasense*, 649 F.3d at 1285).

"The standards for *pleading* a claim of inequitable conduct are more lenient than the standards for obtaining relief." *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-cv-571, 2017 WL 2804953, at *4 (D.N.J. 2017). "At the pleading stage, the proponent of [an] inequitable conduct theory need only plead facts supporting a reasonable inference that a specified individual '(1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.'" *Id.* (quoting *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009)). That includes "'identify[ing] the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.'" *Id.* (quoting *Exergen*, 575 F.3d at 1327). But "[i]t is a mistake to suppose that . . . all the evidence which may be adduced to prove [a] fraud [on the Patent Office] must be recited in" a defendant's counterclaim. *United States v. Am. Bell Tel. Co.*, 128 U.S. 315, 356 (1888). Instead, "[i]t is sufficient if the main facts or incidents which constitute the fraud against which relief is desired shall be fairly stated, so as to put the [patentee] upon his guard, and apprise [it] of what answer may be required of [it]." *Id.*

Thus, at the pleading stage, the proponent of an inequitable conduct claim need ***not*** make "a showing that deceptive intent is the single most reasonable inference." *Depomed*, 2017 WL 2804953, at *4 (citing *Exergen*, 575 F.3d at 1329 n.5). Nor need it secure "a confession by the plaintiff that it 'intended to withhold [material information] from the USPTO.'" *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, No. 00-cv-1167, 2010 WL 1372176, at *6 (D.N.J. 2010). Instead, "deceptive intent" need only be "a reasonable inference," *i.e.*, "'one that is plausible and that flows logically from the facts alleged.'" *Depomed*, 2017 WL 2804953, at *4 (quoting *Exergen*, 575 F.3d at 1329 n.5); *see also Sanders v. The Mosaic Co.*, 418 F. App'x 914, 919 (Fed. Cir. 2011) (same); *Delano Farms Co. v. Cal. Table Grape Comm'n*, 655 F.3d 1337,

1350 (Fed. Cir. 2011) (similar); *Auxilium Pharms., Inc. v. Watson Labs., Inc.*, No. 12-cv-3084, 2013 WL 5503209, at *7 (D.N.J. 2013) (same); *Indus. Tech.*, 2012 WL 4469383, at *4 (denying motion to dismiss inequitable conduct claim where defendants "alleged sufficient facts from which a reasonable juror *could* infer . . . the requisite state of mind").

As discussed below, Sandoz's counterclaims more than plausibly allege facts from which a reasonable juror could conclude that Allergan's omissions and misrepresentations were material to the Patent Office's decision to allow its claims, and could reasonably infer from Allergan's 16 years of prosecution misconduct a specific intent to deceive. In its motion to dismiss, Allergan does little more than register its disagreement with the facts pled, but does not seriously challenge their plausibility. Its motion should be denied.[11]

A. Sandoz Has Plausibly Pled that Allergan Intentionally Submitted a False Affidavit to and Withheld Material Information from the Patent Office

Allergan's efforts to rebut Sandoz's allegations depend heavily on statements made by other courts in earlier cases. According to Allergan, "the court findings of unexpected results in prior cases show that Sandoz's allegations cannot meet the materiality or intent requirements of *Therasense* as a matter of law." Allergan MTD at 23. With respect to *materiality*, Allergan specifically contends that "[t]he finding in the[] prior decisions destroy both the requisite 'but for' requirement and the plausibility of Sandoz's allegations here." *Id.* at 25. With respect to *intent*, Allergan contends that "far from being the 'single most reasonable inference,' as required by *Therasense*, it is completely unreasonable to infer that any of the myriad individuals acted

[11] For the reasons discussed in Sandoz's *Markman* and preliminary injunction briefing, none of the "wherein" clauses in the Asserted Patents limit the scope of their claims. Dkts. 58, 71, 115. Even if, however, those clauses are limiting as "material to patentability," that only heightens Allergan's duty of candor to the Patent Office with respect to those terms. To the extent the Court understands Sandoz's inequitable conduct contentions to suggest the "wherein" clauses are material to patentability, however, Sandoz pleads its inequitable conduct counterclaims as an alternative to its principal position—that the "wherein" clauses are non-limiting.

with the intent to deceive the examiner by making arguments and taking positions with which the courts have agreed." *Id.* Allergan's understanding of the requirements to show inequitable conduct, both on the merits and at the pleading stage, is deeply confused.

First, Allergan's reliance on what other courts may have said about claims in other Combigan-family patents simply cannot undermine the plausibility of Sandoz's counterclaims here. When evaluating whether a patent applicant's non-disclosure or misrepresentation of a reference is "material" for purposes of inequitable conduct, the Federal Circuit has made clear that the relevant question is "whether the *PTO* would have allowed the claim if it had been aware of the undisclosed reference." *Therasense*, 649 F.3d at 1291 (emphasis added). The focus on how the *Patent Office* would have treated the non-disclosed information is critical. During prosecution, Patent Office examiners interpret proposed claims to have "their broadest reasonable construction" and assess their patentability under a "preponderance of the evidence standard." *Id.* at 1291–92. In contrast, district courts generally construe claims more narrowly and evaluate their validity under a "clear and convincing evidence" standard, "a higher evidentiary burden than that used in prosecution at the PTO." *Id.* Thus, "even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO's different evidentiary standards." *Id.* at 1292. For any and all of the reasons laid out in Sandoz's counterclaims and detailed further below, Sandoz has adduced more than sufficient facts to plausibly allege that, had the ***Patent Office*** been made aware of Allergan's repeated omissions and misrepresentations,

odds are that the agency would not have allowed the Asserted Patents' claims. *See* (¶¶ 205–206, 239–244, 260–262, 288–289, 303–304, 323–327, 344–348, 365–367); *infra* Part II.B.[12]

Second, even though Allergan's 16-year pattern of duplicity makes the specific intent to deceive the "single most reasonable inference," Allergan MTD at 25, Sandoz need not prove that to defeat Allergan's motion to dismiss. *See Depomed*, 2017 WL 2804953, at *4 (citing *Exergen*, 575 F.3d at 1329 n.5). Instead, Sandoz need only "allege sufficient facts from which a reasonable juror *could* infer . . . the requisite state of mind." *Indus. Tech.*, 2012 WL 4469383, at *4. Such an inference is simply "'one that is plausible and that flows logically from the facts alleged.'" *Depomed*, 2017 WL 2804953, at *4 (quoting *Exergen*, 575 F.3d at 1329 n.5); *see Sanders*, 418 F. App'x at 919; *Delano*, 655 F.3d at 1350; *Auxilium*, 2013 WL 5503209, at *7.

Sandoz's counterclaims undeniably satisfy that standard. Allergan cannot legitimately dispute that a reasonable juror *could* infer deceptive intent from each and all of the following:

1. Allegan's filing of Dr. Schiffman's affidavit with the PTO, which stated Combigan had no nervous system side effects when Dr. Schiffman knew that was not true, (¶¶ 211–249);

[12] Allergan's argument that "issue preclusion should bar Sandoz from challenging unexpected results" is equally meritless. Allergan MTD at 23. For purposes of inequitable conduct, the question is ***not*** whether Allergan can prove unexpected results in ***court***, but instead whether information that Allergan withheld from or misrepresented to the ***Patent Office*** would have been material to the agency's decision to issue the patent. Indeed, because, when assessing patentability, the Patent Office applies the more lenient preponderance-of-evidence standard, district-court determinations of no invalidity applying the more stringent clear-and-convincing-evidence standard should ***not*** have preclusive effect in the PTO. *See United States v. One Assortment of 89 Firearms*, 465 U.S. 354, 361–62 (1984); *One Lot Emerald Cut Stones v. United States*, 409 U.S. 232, 492 (1972); *U.S. Aluminum Corp./Texas v. Alumax, Inc.*, 831 F.2d 878, 881 (9th Cir. 1987) ("Aluminum's burden in this action is to establish malice by a preponderance of the evidence. Consequently, Aluminum is not collaterally estopped by its failure to establish, in the previous litigation, bad faith by clear and convincing evidence"); 18 Charles Alan Wright et al., Federal Practice and Procedure § 4422 (3d ed. 2018) ("Failure to carry a special burden of persuasion characterized as requiring clear and convincing evidence or some like showing does not preclude a later attempt to prove the same issue by a preponderance of the evidence . . .").

2. Allergan's filing of clinical-trial data on Combigan's safety to the PTO, when the FDA told Allergan that the data did not support Allergan's asserted safety results, (¶¶ 292–306);

3. Allergan's initial withholding and later burial of the FDA's detailed discussions of the flaws in Allergan's clinical studies, (¶¶ 266–291);

4. Allergan's non-disclosure of papers its own scientists authored, which contradicted arguments to the PTO that its claimed "inventions" had unexpected results, (¶¶ 307–330);

5. Allergan's non-disclosure of the opinions of its own experts from a prior litigation that contradicted the positions Allergan took in the PTO, (¶¶ 250–265);

6. Allergan's selective submission of clinical-trial data that supported its unexpected-results arguments, while omitting data that contradicted those arguments, (¶¶ 331–351);

7. Allergan's withholding of clinical-trial data that showed that decreasing the frequency of brimonidine administration resulted in fewer side effects, (¶¶ 331–351); and

8. Allergan's tactic, when it finally decided to disclose some previously withheld material information, to do so by burying it within hundreds of other documents, (¶¶ 352–375).

The table presented on pages 12–15 of Allergan's opening brief sets forth even more of examples of Allergan's prosecution misconduct, committed by specific individuals—Brent Johnson, John Wurst, Lorenz Siddiqi, and Rhett Schiffman—over the past 16 years. Allergan MTD at 12–15.

Importantly, and as all of the above illustrates, Sandoz's allegations of inequitable conduct do not depend on any single example of Allergan's prosecution misconduct. Well before Allergan applied for the first Combigan-family patent, it recognized that "[n]o patent protection [was] available" for the Combigan formulation. (¶ 37); Ex. 37, *207* Dkt. 343, 10/26 PM Tr. (Gryziewicz) at 41:21–42:2, 42:15–19. Yet Allergan sought patent protection regardless, and a reasonable juror could infer that Allergan's strong commercial incentives to obtain exclusive rights to Combigan inspired it to deceive the Patent Office time and again over most of the past two decades. (¶¶ 457–465). Sandoz's ongoing discovery efforts relating to its inequitable conduct claims may provide even more evidence of Allergan's wrongdoing. At this early stage

in the proceedings, however, Sandoz's detailed pleadings easily present a plausible case for inequitable conduct that Allergan's motion to dismiss cannot defeat. (¶¶ 10–16).

B. Each Basis of Inequitable Conduct Alleged by Sandoz is Plausible

Allergan's piecemeal response to Sandoz's inequitable-conduct claims misunderstands Sandoz's argument. Allergan MTD at 26. Sandoz's inequitable-conduct argument does not depend on any one example of Allergan's prosecution misconduct, but instead alleges a pattern of material wrongdoing from which a juror could reasonably infer a specific intent to deceive the Patent Office. *See supra* Part II.A. In any event, and for the reasons below, each of Allergan's arguments fails on its own terms.

1. Allergan Submitted the Material and False Schiffman Declaration with a Specific Intent to Deceive the PTO (Basis 2) (¶¶ 211–249)

One of the starkest examples of Allergan's inequitable conduct is its submission of the unquestionably false declaration from Dr. Schiffman, Allergan's Vice President of Ophthalmology. Dr. Johnson, one of Allergan's prosecuting attorneys, first submitted Dr. Schiffman's declaration during prosecution of the '149 patent. When the declaration was submitted, Allergan had already conducted ***both*** the 019T study ***and*** the 507T study, and Dr. Schiffman was aware of ***both***. (¶¶ 155, 214–215); Ex. 41, AGN_COM00671353 (Jan. 2003 memo to Schiffman regarding the 507T trial). The data from the 507T study showed that Combigan produced *more* nervous-system side effects than did serial administration of brimonidine and timolol BID. (¶¶ 75, 213, 222). Dr. Schiffman's declaration, however, stated that the "percentage of patients in the Combination [*i.e.*, Combigan] group experiencing adverse events of the nervous system" was unexpectedly "***0.0%***," presenting data only from the 019T study. (¶ 212). Moreover, Dr. Schiffman's declaration did not disclose that he was an Allergan employee, much less a high-level executive. (¶¶ 216–217).

Allergan has "no room to argue that submission of [Dr. Schiffman's] false affidavit[] is not material" for inequitable conduct. *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983); *see Intellect Wireless, Inc. v. HTC Corp.*, 732 F.3d 1339, 1342–44 (Fed. Cir. 2013) ("*Therasense* in no way modified *Rohm & Haas*'s holding that the materiality prong of inequitable conduct is met when an applicant files a false affidavit and fails to cure the misconduct."). "After all," Allergan was "unlikely to go to [such] great lengths to deceive the PTO with [that] falsehood unless it believe[d] that the falsehood w[ould] affect issuance of the patent." *Therasense*, 649 F.3d at 1292. Compounding Allergan's misconduct, the "omission of a declarant's employment with [the] inventor's company [is] 'inherently material.'" *Id.* (quoting *Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1583 (Fed. Cir. 1996)).

Allergan does not dispute that Dr. Schiffman's declaration was false and wrongfully failed to disclose Dr. Schiffman's employment at Allergan. Instead, Allergan claims that it (much) later corrected those misrepresentations.[13] But Sandoz has alleged at least a plausible case that Allegan did no such thing. To cure inequitable conduct, "[i]t does not suffice that one knowing of misrepresentations in an application or in its prosecution merely supplies the examiner with accurate facts without calling his attention to the untrue or misleading assertions sought to be overcome, leaving him to formulate his own conclusions." *Rohm & Haas*, 722 F.2d at 1572. Instead, the applicant must, among other things, "expressly advise the PTO of [the misrepresentation], stating specifically where it resides," and "advise [the PTO] what the actual facts are." *Id.*

[13] A juror could also infer that the only reason Allergan attempted to back-track its patently false statements was because it knew it could not prevent the 507T clinical trial data from becoming public—had this data not threatened to become public, Allergan likely never would have attempted to whitewash its prior deception.

Allergan, however, never actually submitted the clinical-trial data from the 507T study, but instead submitted only a summary manuscript prepared by Dr. Goni. (¶¶ 49, 219 n.9). Allergan never disclosed that the FDA criticized the 019T study—whose data Dr. Schiffman initially presented—as insufficient to show that Combigan was as efficacious as serial brimonidine and timolol, or "to determine the adverse event profile [of Combigan] due to the [study's] short duration." Ex. 22, Medical Review, Part II at 52. And although Allergan mentioned Dr. Schiffman's employment at Allergan to the PTO, it did so only in passing ***more than one year after*** submitting his declaration, in a wholly unrelated filing. *See* (¶ 216). Making matters worse, when Allergan later re-submitted Dr. Schiffman's declaration during the prosecution of several other Combigan-family patents, it continued to omit Dr. Schiffman's employment relationship with Allergan. (¶ 217 n.8). Because the examiners of the '149 patent were different from the examiners of some of the later-prosecuted patents, it is more than plausible that Allergan's identification of Dr. Schiffman's employment in the former prosecution did not notify the examiners in the latter ones. *Compare* Ex. 5 ('149 patent, cover; examiners C. Low and B. Kwon), *with* Ex 8 ('409 patent, cover; examiner B.-S. Baek).

At a minimum, Sandoz has plausibly alleged that a reasonable juror *could* conclude that the false declaration was but-for material to the Patent Office's decision to allow Allergan's patents. Allergan's arguments otherwise confuse the standards for *pleading* inequitable conduct and proving it at trial. Allergan MTD at 29. The Patent Office Examiner did not explain why he allowed the '149 patent's claims. (¶ 163). But Allergan continued to submit the Schiffman declaration when prosecuting other Combigan-family patents, and the Patent Office examiners of several of those patents—often different examiners for different patents, *see supra*—allowed their claims precisely because they found the claimed inventions achieved the type of

"unexpected results" falsely described in Dr. Schiffman's declaration. *See, e.g.,* Ex. 31 at 12 (disclosure of Schiffman declaration during prosecution of the '409 patent); *id.* at 3 (Examiner allowing claims because Allergan purportedly "showed unexpected results (less nervous system side effects such as somnolence)"); Ex. 30 at 10, 13 (same, for '890 patent).

Allergan nonetheless contends that the Schiffman declaration is immaterial because the examiners purportedly allowed Allergan's patents based on additional evidence. But that is at most a question "concerning the degree of the materiality of the" Schifmann declaration, which is "more appropriately considered on a more developed record" and cannot defeat Sandoz's allegations at this early stage. *Indus. Tech.*, 2012 WL 4469383, at *5 (citing *Mars Inc. v. JCM Am. Corp.*, No. 05-cv-3165, 2006 WL 1704469, at *8-9 (D.N.J. 2006)). From discovery Sandoz has conducted thus far, it has plausibly alleged that Allergan submitted the Schiffman declaration because it did not think the Patent Office would ever learn of the 507T clinical trial. Instead, it was only after Allergan's prosecution counsel, Dr. Johnson, learned that Dr. Goni was going to publish the results of the 507T study that he informed the Patent Office that the study's results had come to "Applicant's [*i.e.*, Allergan's]" attention. Ex. 40, Wurst Dep. Tr. at 228:3–8.[14] Sandoz has plausibly alleged that Dr. Johnson's response was both false and insufficient to cure Dr. Schiffman's false declaration, which was material to the Patent Office's decision to allow Allergan's claims. The Court should deny Allergan's motion to dismiss for that reason alone.[15]

[14] *See supra* note 3.

[15] As noted in Sandoz's opposition to Allergan's PI motion, this is not the first time Dr. Schiffman has been accused of inequitable conduct based on a declaration he submitted to the Patent Office (much less the first time Allergan has been accused). *See* Dkt. 115 at 29 n.9.

2. Allergan Failed to Disclose the Material Duh Report with the Specific Intent to Deceive the PTO (Basis 3) (¶¶ 250–265)

Allergan's pattern of prosecution misconduct continued with its non-disclosure of Dr. Duh's report on the results of Allergan's Combigan clinical studies. The '453 and '802 patents asserted here each recite that Combigan is as effective as brimonidine TID. (¶¶ 250, 255). During prosecution, Allergan argued that Combigan unexpectedly performed at least as well as brimonidine TID at all time-points during the 012T study. (¶¶ 291–295). Allergan does not dispute, however, that Dr. Duh concluded otherwise in her report: "In ocular hypertension patients, the mean IOP reductions from baseline were greater in the Brimonidine group than in the combination [Combigan] group at hour 9 at all follow-up visits." (¶ 119); Ex. 35, *207* Dkt. 341, 10/25 PM Tr. (Noecker) at 104:22–105:3. Because the Examiner allowed the claims of the Asserted Patents based on the claimed inventions' supposedly unexpected results, Sandoz has made out at least a plausible case that Allergan's failure to disclose Dr. Duh's report was a material omission made with the specific intent to deceive.

Allergan's arguments otherwise again ignore the standard for adequately pleading inequitable conduct. ***First***, Allergan argues that Sandoz's allegations based on Dr. Duh's report are "merely Sandoz's view of the data." Allergan MTD at 30. Although Sandoz's view of Dr. Duh's data is correct, Allergan's argument, again, at most "concern[s] the degree of the materiality of the" non-disclosure of Dr. Duh's report, an issue that is "more appropriately considered on a more developed record" and is insufficient to defeat Sandoz's allegations at the pleadings stage. *Indus. Tech.*, 2012 WL 4469383, at *5.

Second, Allergan emphasizes that Dr. Duh reported "'no statistically significant differences in the mean IOP reductions from baseline between Combination [*i.e.* Combigan] and Brimonidine.'" Allergan MTD at 30. But none of the Asserted Patents' claims requires that

Combigan be "statistically significantly" as effective as brimonidine TID. And it violates basic claim-construction principles to read in such a requirement where, as here, the patentee deliberately chose not to use language of "statistical significance" in the claims themselves. *See, e.g.*, *Iovate Health Sci., Inc. v. Allmax Nutrition, Inc.*, 639 F. Supp. 2d 115, 119-20 (D. Mass. 2009). "[B]ecause the term 'statistical[ly] significan[t]' is used in the specification to describe the" comparison between the efficacy of Combigan and brimonidine TID, "but is omitted from the disputed claims," "as effective as" should "be read as just that and without the limitation of being 'statistically significant.'" *Id.* at 120. Allergan does not dispute that Dr. Duh reported that, as a numerical matter, Combigan performed ***worse*** than brimonidine TID at some time points. That is more than enough to plausibly allege that Allergan's non-disclosure of Dr. Duh's report would have been material to the Examiner.[16]

Third, Allergan argues that it is implausible that Mr. Siddiqi specifically intended to deceive the Patent Office with respect to the Asserted Patents, because "he was simply not aware of [Dr. Duh's] report." Allergan MTD at 31. Allergan's argument is not credible, much less sufficient to defeat Sandoz's inequitable conduct allegations at this early stage. Mr. Siddiqi knew of the prior litigations between Allergan and Sandoz, *see* Ex. 39, Siddiqi Dep. Tr. at 26:5–14, and he cited several materials from those litigations in Information Disclosure Statements to

[16] Because none of the claims of the Asserted Patents use language of "statistical significance," the Patent Office would be especially unlikely to read in such a requirement. Unlike district courts, which "give claims their 'ordinary meaning . . . as understood by a person of skill in the art,'" PTO examiners are required to "give a patent claim 'its broadest reasonable construction in light of the specification of the patent in which it appears.'" *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142–46 (2016) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc); 37 C.F.R. § 42.100(b)). By definition, the broader a patent claim's construction, the fewer limitations (like "statistically significant") it has.

the Patent Office. (¶ 179).[17] Moreover, Mr. Siddiqi had a duty to reasonably investigate the evidence from the earlier litigations when prosecuting the Asserted Patents, and he knew that expert reports were submitted in those litigations. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1383-85 (Fed. Cir. 2001); Ex. 39, Siddiqi Dep. Tr. at 253:2–15. In short, Mr. Siddiqi continued Allergan's 16-year pattern of prosecution misconduct by withholding or selectively ignoring Dr. Duh's report. (¶¶ 250–265). Sandoz has plausibly alleged the same in its inequitable conduct counterclaims, and Allegan's motion to dismiss should be denied.

3. Allergan Misrepresented to the PTO Combigan's Performance Compared to the "Closest Prior Art" (Basis 1) (¶¶ 185–210)

Allergan's prosecuting attorneys also misled the Patent Office about the scope and content of the prior art and knowingly failed to identify the "closest prior art." (¶ 183). Allergan does not dispute that its attorneys acted unreasonably in comparing the results of the claimed "invention" (brimonidine and timolol BID, from the ***same*** bottle) to brimonidine TID—as opposed to what was unquestionably closer prior art (brimonidine and timolol BID, from ***separate*** bottles). Instead, Allergan contends that what its attorneys argued to the Patent Office cannot be material for purposes of inequitable conduct. Allergan MTD at 26–27. That is simply not true. Even "'[t]ruthful statements'" by an attorney can evidence inequitable conduct where those statements are "'crafted in a misleading manner through intentional omission of particular relevant facts.'" *Depomed*, 2017 WL 2804953, at *6 (quoting *B.F. Goodrich Co. v. Aircraft*

[redacted]

Braking Sys. Corp., 72 F.3d 1577, 1585 (Fed. Cir. 1996)); *Transclean Corp. v. Bridgewood Servs., Inc.*, 77 F. Supp. 2d 1045, 1089 (D. Minn. 1999), *vacated on other grounds*, 290 F.3d 1364 (Fed. Cir. 2002). That is exactly what Allergan did here. For example, Allergan's prosecuting attorneys never disclosed to the Patent Office that ophthalmologists in the United States routinely prescribed twice-daily administration of brimonidine (outside of Combigan) for lowering IOP. (¶ 203). A reasonable juror could plausibly find that omission to be material.

Allergan's argument that Sandoz has failed to show a specific intent to deceive the Patent Office is equally meritless. Sandoz's allegations present much more than a "bald conclusion" of intent based on the materiality of Allergan's omissions. Allergan MTD at 28. Again, Allergan misleadingly casts Sandoz's argument as based on a single act of prosecution misconduct. *Id.* (selectively quoting ¶ 210). But Sandoz contends that a ***pattern*** of omissions and misrepresentations, along with the individual events, shows Allergan's inequitable conduct. (¶ 210) ("Even if one or two omissions or misrepresentations can be ascribed to gross carelessness or oversight, Allergan's repeated conduct over many years and multiple omissions and misrepresentations demonstrate that the only plausible reasons such omissions and misrepresentations were made was because they were part of an active plan to deceive the PTO."). That is sufficient to state a claim for at least "infectious inequitable conduct," *i.e.*, that Allergan has engaged in a "'broad pattern of inequitable conduct,'" such that all of its patents with an "immediate and necessary relation" to each other are unenforceable based on the "unenforceability [of at least] one patent" in the family. *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 522, 537-39 (D.N.J. 2000) (quoting *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245 (1933), and *Consol. Aluminum Corp. v. Fonseco Int'l Ltd.*, 910 F.2d 804, 810 (Fed. Cir. 1990)); *see eSpeed, Inc. v. Brokertec USA, L.L.C.*, 417 F. Supp. 2d 580,

595-96 (D. Del. 2006). Allergan's silence on Sandoz's pattern-of-misconduct arguments reinforces the plausibility of Sandoz's inequitable conduct allegations.

4. Allergan Failed to Disclose Material Clinical Data and FDA Criticisms with Specific Intent to Deceive the PTO (Bases 1, 2, 4, 5, 7, 8) (¶¶ 185–210, 211–249, 266–291, 292–306, 331–351, 352–369)

In one fell swoop, Allergan attempts to dispose of six separate allegations of inequitable conduct involving Allergan's failure to disclose information from several sources, including the 012T and 023T studies, the FDA's Medical Reviews of Combigan, and the Final Report for Alphagan. Allergan MTD at 31–32. Allergan does not, however, dispute any of the following:

1. The withheld data from the 012T clinical study contradicted or was less favorable than the data from the 013T study with respect to the same adverse events that Allergan's prosecuting attorneys argued to the Examiner showed unexpected results, (¶¶ 331–351);

2. Allergan failed to disclose the FDA's Medical Reviews of Combigan during prosecution of at least three Combigan-family patents, even though those Medical Reviews contained the FDA's repeated and vigorous criticisms of the very same clinical trials and data that Allergan relied on in arguing for patentability, (¶¶ 223, 266–306);

3. Allergan withheld the Final Report for Alphagan from the Patent Office, even though that report indicated that there were no clinical differences between brimonidine TID and BID, and that there were significantly fewer side-effects with the BID regimen, (¶ 224);

4. Allergan presented data from clinical trials, such as the 023T trial, that the FDA rejected as failing to show that Combigan was as effective as serial administration of brimonidine and timolol, (¶¶ 266–291); and

5. Allergan repeated the above omissions and misrepresentations—each of which played a pivotal role in the Patent Office's decision to allow the claims, (¶¶ 169–182)—throughout its prosecution of the Combigan-family patents, (¶¶ 370–375).

Allergan nonetheless asks the Court to brush aside these undisputed facts as allegedly immaterial, arguing that "***courts*** have found unexpected results after seeing the data in all of" the above materials. Allergan MTD at 31 (emphasis added). But, as discussed above, the relevant question for inequitable conduct is ***not*** whether a court applying the clear-and-convincing-evidence standard found invalidity. *See supra* Part II.A. Instead, it is whether the ***Patent Office***

applying the preponderance-of-the-evidence standard would find the information material. *Therasense*, 649 F.3d at 1291-92 ("even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO's different evidentiary standards").

Making matters worse for Allergan, it is equally irrelevant with respect to intent whether Allergan's prosecuting attorneys "advanced arguments" to the Patent Office "that ultimately would either be accepted in Court in the future . . . or had already been accepted in Court." Allergan MTD at 32. That is a non-sequitur: Even if some of the arguments about unexpected results that Allergan's prosecuting attorneys made in the Patent Office were later accepted by some courts, that does not mean that those attorneys acted without an intent to deceive, especially in view of their repeated omissions of material information. At a minimum, Allergan's failure to contest any of the above factual allegations makes plain the plausibility of Sandoz's inequitable conduct counterclaims.

5. Allergan Failed to Disclose the Material David Reference with the Specific Intent to Deceive the PTO (Basis 6) (¶¶ 307–330)

In 2001, Dr. Robert David, Senior Medical Director at Allergan's Ophthalmology Clinical Research Department, authored an article that reviewed and analyzed data collected from various long-term clinical studies involving the serial administration of brimonidine and timolol BID—which is undoubtedly the closest prior art to the regimen claimed in the Asserted Patents. (¶¶ 188, 310–314). Allergan does not dispute that David teaches each of the following:

1. Serial, BID administration of brimonidine and timolol (from separate bottles) was "an agent of choice" for treating elevated intraocular pressure as early as 2001, (¶ 188);
2. The efficacy of a brimonidine BID regimen increases over time, and the incidence of allergic conjunctivitis (an adverse event recited in the claims of the Asserted Patents) for that regimen decreases over time, (¶ 311); and

3. Administering brimonidine BID is more effective long-term than is administering brimonidine TID, (¶ 312).

Although each of the above teachings directly undermines Allergan's arguments to the Patent Office that its claimed regimen achieves unexpected results compared to the closest prior art, Allergan admits that it never once submitted the David reference to the Patent Office during the 16 years that it has been prosecuting Combigan-family patents. Allergan MTD at 32-33.

Allergan nonetheless suggests that its failure to disclose David to the Patent Office is immaterial, since David was allegedly cumulative of other prior art that Allergan submitted to ***courts*** during the earlier litigations. Allergan MTD at 32–33. Again, that is irrelevant: For inequitable conduct, the question is what Allergan submitted to the ***Patent Office***. *See supra* Part II.A. On that question, Allergan argues only that some of the references cited in David were also submitted to the Patent Office; but Allergan does not contend that those references disclose each of David's material teachings. Allergan MTD at 33. Nor does Allergan say anything about the several references cited in David that Allergan never submitted to the PTO. And Allergan still offers no explanation for why, to this day, it has not submitted the David reference to the Patent Office. As with each of the other bases discussed above, Sandoz has sufficiently alleged that Allergan's failure to disclose the David reference to the Patent Office was material and committed with the specific intent to deceive.

6. Allergan Buried Material Information with the Specific Intent to Deceive the PTO (Basis 8) (¶¶ 352-369)

When prosecuting later Combigan-family patents, including those asserted here, Allergan eventually disclosed some of the material information that it initially withheld—including the FDA's Medical Review of Combigan and the Final Report on Alphagan. Allergan does not dispute, however, that it "disclosed" those previously omitted references as exhibits to a massive Information Disclosure Statement that listed hundreds of references. Allergan MTD at 31–32.

Several courts have found such "'burying'" of material prior-art references "can state a claim for inequitable conduct," and have therefore denied motions to dismiss on that basis. *Coolsystems, Inc. v. Nice Recovery Sys. LLC*, No. 16-cv-02958, 2016 WL 6091577, at *4 (N.D. Cal. 2016) (collecting cases and denying motion to dismiss inequitable conduct allegations where disputed material information was submitted with 176 other prior-art references); *see also Nomadix, Inc. v. Hosp. Core Servs. LLC*, No. 14-cv-08256, 2015 WL 3948804, at *9 (C.D. Cal. 2015); *CIVIX-DDI, LLC v. Hotels.com, L.P.*, 711 F. Supp. 2d 839, 848–49 (N.D. Ill. 2010). Indeed, the Manual of Patent Examining Procedure ("MPEP"), a guide for Patent Office prosecution, states that if a "long list [of references] is submitted," the patent applicant should "highlight those documents which have been specifically brought to applicant's attention and/or are known to be of most significance." MPEP § 2004. That admonition has particular force where, as here, the cited references call into question the accuracy or reliability of data previously relied on by the applicant in arguing for patentability. But Allergan did not highlight the damning information; it buried it in 240 references, with no highlighting whatsoever. *See* (¶ 254 n.15); Ex. 32.

Allergan gives short shrift to Sandoz's "burying" allegations, arguing that they somehow "highlight the internal inconsistency in Sandoz's positions." Allergan MTD at 33. According to Allergan, the "far more reasonable inference" is that Allergan sought to "meet [its] duty of candor." *Id.* Nonsense. Allergan ignores its litany of other omissions and misrepresentations, as identified above and in Sandoz's counterclaims. The prior art references and other information that Allergan initially withheld from the Patent Office were not only material to patentability, but in many cases contained information that directly contradicted arguments that Allergan's prosecuting attorneys made to the Patent Office. Allergan cannot cure those serial omissions and misrepresentations simply by burying purportedly curative information within a mass of

hundreds of other, marginally relevant (at best) documents. For that and all of the other reasons discussed above, Sandoz has more than sufficiently alleged the who, what, when, where, and how of Allergan's inequitable conduct. Allergan's motion to dismiss should be denied.

III. SANDOZ'S ANTITRUST CLAIMS ARE PLAUSIBLE

Allergan's arguments regarding Sandoz's antitrust claims are similarly flawed and do not support dismissal on the pleadings. As an initial matter, Allergan incorrectly lumps all three of Sandoz's federal antitrust counterclaims together as involving "sham litigation," when in fact only Sandoz's 17th counterclaim does so. Sandoz's 15th counterclaim pleads *Walker Process* fraud, a separate antitrust violation under Section 2 of the Sherman Act. *Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172 (1965). This claim pleads the fraudulent procurement and enforcement of the '453, '801, and '802 patents, and does not include or require any allegation of "sham" litigation.[18]

Sandoz's 16th counterclaim is similarly independent from its sham litigation claim, as it alleges a "pattern" of monopolistic conduct as part of an overall scheme to monopolize (including multiple anticompetitive acts). *See* (¶ 73). This claim likewise does not require allegations of "sham litigation," and is based on Allergan's overall scheme of conduct. The Third Circuit has specifically upheld such claims where "liability is not found based on

[18] Allergan half-heartedly argues that Sandoz's *Walker Process* claim should be time-barred, but it clearly is not. The antitrust statute of limitations is generally four years, but Sandoz bases its claims on the recently issued '453, '801, and '802 patents, which are well within the relevant statute of limitations. Moreover, the Third Circuit has repeatedly recognized that a statutory violation, including of the antitrust laws, *continues* for the entire duration of the anticompetitive effects of a party's monopolistic practices under the "continuing violation" doctrine. *See, e.g., Brenner v. Local 514 United Bros. of Carpenters of Am.*, 927 F.3d 1283, 1295 (3d Cir. 1991) ("In most federal causes of action, when a defendant's conduct is part of a continuing practice, an action is timely so long as the last act evidencing the continuing practice falls within the limitations period."); *Toledo Mack Sales & Serv., Inc. v. Mack Trucks, Inc.*, 530 F.3d 204, 217–18 (3d Cir. 2008) (applying continuing violation doctrine to antitrust claims).

individual acts," but rather "on the acts taken together." *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 428 (D. Del. 2006); *see also LePage's, Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003) ("The relevant inquiry is the anticompetitive effect of [defendant's] exclusionary practices considered together . . . . the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation."); *In re Neurontin Antitrust Litig.*, No. 02-cv-1390, 2009 WL 2751029, at *15 (D.N.J. 2009) ("Courts have routinely upheld the validity of 'overall monopolization scheme' claims in the patent context, even in the absence of allegations that any one of the scheme's predicate actions was independently violative of antitrust laws.").[19]

As to Sandoz's sole counterclaim that does assert "sham litigation," Allergan misstates both the law and Sandoz's contentions. Allergan cites *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993), to argue that Sandoz must show that Allergan's multiple lawsuits were each "objectively baseless." Allergan MTD at 34. Allergan, however, ignores Third Circuit and other consistent precedent holding that where, as here, a *series* of proceedings are brought to thwart competition, a claimant need not show each was "objectively baseless." *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162 (3d Cir. 2015); *see Cal. Motor Transp. v. Trucking Unlimited*, 404 U.S. 508 (1972); *Waugh Chapel S., LLC v. United Food & Commercial Workers Union Local 27*, 728 F.3d 354 (4th Cir. 2013); *Primetime 24 Joint Venture v. Nat'l Broad. Co.*, 219 F.3d 92 (2d Cir. 2000); *USS-POSCO Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council*, 31 F.3d 800 (9th Cir. 1994).

These precedents have allowed sham litigation claims in the case of repetitive claims without proving each was objectively baseless; in fact, it is conceivable that some claims may be

[19] Allergan's argument that Sandoz's pattern-of-conduct claim is based solely on sham litigation allegations is inaccurate. The counterclaim raises a pattern of intentional conduct and is not limited to the assertion that any one litigation was sham. *See, e.g.*, (¶ 73).

successful. "The fact that there may be moments of merit within a series of lawsuits is not inconsistent with a campaign of sham litigation, for 'even a broken clock is right twice a day.'" *Waugh*, 728 F.3d at 365 (citations and quotations omitted). Accordingly, when a pattern or series of litigations is at issue, the plaintiff *need not* prove that all claims were "objectively baseless" but rather that, based on a "holistic" approach and the totality of circumstances, the multiple ligations were intended to thwart competition. *Hanover*, 806 F.3d at 180. In short, "a more flexible standard is appropriate when dealing with a pattern of petitioning." *Id.*[20]

This standard is based on the Supreme Court's decision in *California Motor*, which did not require an "objectively baseless" threshold. Rather, in the litigation context, the Court held that the complaint demonstrated a sham because it contained allegations that respondents "sought to bar their competitors from meaningful access to adjudicatory tribunals and . . . to usurp the decisionmaking process" by instituting proceedings "with or without probable cause, and regardless of the merits of the cases." *California Motor*, 404 U.S. at 512. Accordingly, the *PRE* "objectively baseless" requirement is not appropriate here. As the Ninth Circuit has explained:

> *California Motor Transport* deals with the case where the defendant is accused of bringing a whole series of legal proceedings. Litigation is invariably costly, distracting and time-consuming; having to defend a whole series of such proceedings can inflict a crushing burden on a business. *California Motor Transport* thus recognized that the filing of a whole series of lawsuits and other legal actions without regard to the merits has far more serious implications than filing a single action, and can serve as a very effective restraint on trade. When dealing with a series of lawsuits, the question is not whether any one of them has merit—some may turn out to, just as a matter of chance—but whether they are brought pursuant to a policy of starting legal proceedings without regard to the

[20] Allergan claims in a footnote that the "series" test outlined by the Third Circuit in *Hanover* was abrogated by *In re Wellbutrin XL Antitrust Litigation Indirect Purchaser Class*, 868 F.3d 132, 157 (3d Cir. 2017). That contention is baseless. As an initial matter, *Wellbutrin* dealt with only *two* instances of patent enforcement, which was one of the bases for the Court's decision to apply the *PRE* test. In addition, *Wellbutrin* involved, and discussed in the context of Hatch-Waxman, the issue of serial litigation against multiple generics, not a situation where, like here, Allergan has engaged in serial litigation against one specific generic (Sandoz). 868 F.3d at 137.

> merits and for the purpose of injuring a market rival. The inquiry in such cases is prospective: Were the legal filings made, not out of a genuine interest in redressing grievances, but as part of a pattern or practice of successive filings undertaken essentially for purposes of harassment?

POSCO, 31 F.3d at 811.

That is precisely the type of conduct about which Sandoz complains here. (¶¶81–99 (pp. 182–84)). In such cases, the *PRE* "objectively baseless" standard does not apply. Instead, the analysis focuses on the "pattern of the legal proceedings, not their individual merits." *Waugh*, 728 F.3d at 364. Sandoz has adequately alleged that Allergan has engaged in such a pattern, and the fact that some of Allergan's claims may have been found to have some merit does not preclude Sandoz's claim.[21]

Finally, Allergan's alternative request that the Court bifurcate and stay Sandoz's antitrust claims should be rejected given the substantial potential overlap between Sandoz's patent and antitrust claims. Courts routinely decline to bifurcate claims that involve substantially overlapping issues. *See, e.g.*, *In re Theodor Groz & Sohne*, 972 F.2d 1352, at *2 (Fed. Cir. 1992) (table) (upholding denial of motion to sever because "the commonality of the patent and antitrust issues presented made severance and stay of discovery an unworkable and inefficient use of judicial resources"); *Nationwide Mut. Ins. Co. v. Garzone*, No. 07-cv-4767, 2009 WL 2996468, at *25 (E.D. Pa. 2009) (factors to consider for severance include "whether the issues sought to be tried separately are significantly different from one another [and] . . . whether the separable issues require the testimony of different witnesses and different documentary proof"). Here,

[21] Sandoz's remaining antitrust claim—under New Jersey state law—also states a plausible claim for relief. As Allergan recognizes, the New Jersey Antitrust Act is interpreted in harmony with the Sherman Act. Allergan MTD at 38 n.15. Accordingly, Sandoz's 18th counterclaim is plausible for the same reasons as Sandoz's federal antitrust claims.

there is considerable overlap between Sandoz's patent and antitrust claims, making bifurcation and/or stay an inefficient and inappropriate approach in this case.

CONCLUSION

For the foregoing reasons, the Court should deny Allergan's Motion to Dismiss.

DATED: June 29, 2018

Respectfully submitted,

/s/ Christina L. Saveriano

Christina L. Saveriano
Eric I. Abraham
HILL WALLACK, LLP
21 Rozel Road
Princeton, NJ 08543
Telephone: (609) 924-0808
Facsimile: (609) 452-1888